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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,801	10/16/2003	Shibnath Ghosal	4822-129 US	7933

26817 7590 02/20/2007

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EXAMINER	
HUYNH, CARLIC K	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,801	GHOSAL, SHIBNATH	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *28-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27 and 30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 February 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-35 are pending in the application, with claims 28-29 having been withdrawn from consideration, in response to the restriction requirement submitted on November 2, 2006. Accordingly, claims 1-27 and 30-35 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election with traverse of Group I, namely claims 1-27 and 30-35, in the reply filed on November 30, 2006 is acknowledged. The traversal is on the ground(s) that the search for the system of Group I would uncover the method of Group II. This is not found persuasive because many products can be used with the process of Group II and thus the search for the products of Group I will not necessarily yield the process of Group II. Furthermore, if the product claims of Group I are found allowable, then the process claims of Group II will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai.*

Claims 28-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on November 30, 2006.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on February 5, 2007 is acknowledged.

It is noted that the U.S. Patent No. 5,087,024 is incorrect. The U.S. Patent No. is 5,087,624.

Claim Objections

3. Claim 33 is objected to because of the following informalities: typographical errors. "Dimer" in the instant claim is spelled incorrectly. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-27 and 30-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment, does not reasonably provide enablement for prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex*

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parte Forman, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to a composition for the treatment, prevention or management of a condition in primates, especially humans comprising a phenolic antioxidant-chromium complex.

(2). ***State of the Prior Art***:

The skilled artisan would view that the prevention of a condition is highly unlikely.

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the art of treatment with phenolic antioxidant-chromium complexes is extremely high.

(4). ***Predictability of the Art***:

Prevention is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*,

427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass a composition for the treatment, prevention, or management.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to a composition for prevention is limited.

The disclosure of a composition for treatment is adequate (example 4, pages 29-34).

(7). ***Working Examples***:

For treatment, the working examples in the specification show a decrease in serum glucose levels (Table 1, page 30), in blood sugar values (Table 2, page 32), and in the rate of increase in blood glucose levels (Table 4, page 33), as well as a protective effect against loss of body weight due to hyperglycemia (Table 3, page 33). Thus, the working examples show a composition for the treatment, not prevention, of a condition.

Note that lack of a working example for prevention is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support for prevention. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any phenolic antioxidant-chromium complex having the function recited in the instant claims suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

5. Claims 1-27 and 30-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Type 2 diabetes, does not reasonably provide enablement for other conditions encompassed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). ***Nature of the Invention***:

The rejected claim(s) is/are drawn to an invention which pertains to a composition for the treatment, prevention or management of a condition comprising a phenolic antioxidant-chromium complex.

(2). ***State of the Prior Art***:

The skilled artisan would be able to treat a specific condition (e.g. type 2 diabetes).

(3). ***Relative Skill of Those in the Art***:

The relative skill of those in the arts of type 2 diabetes is extremely high.

(4). ***Predictability of the Art***:

The treatment of any condition is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(5). ***Breadth of the Claims***:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass a composition for the treatment of any condition.

(6). ***Direction or Guidance Presented***:

The guidance given by the specification as to the condition is limited.

The disclosure of the condition as type 2 diabetes is adequate (example 4, pages 29-34).

(7). ***Working Examples***:

For the condition as type 2 diabetes, the working examples in the specification show a decrease in serum glucose levels (Table 1, page 30), in blood sugar values (Table 2, page 32), and in the rate of increase in blood glucose levels (Table 4, page 33), as well as a protective effect against loss of body weight due to hyperglycemia (Table 3, page 33). Thus, the working examples show type 2 diabetes as a condition, not any condition.

Note that lack of any condition is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.

(8). ***Quantity of Experimentation Necessary***:

The specification fails to provide sufficient support of any condition. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any condition having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidence, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without ***undue experimentation***.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1, 12, 14, and 34-35 recite the broad recitation primates, and the claims also recite humans, which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5, 9-11, 22, 24-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghosal (U.S. Patent Application No. 2003/0198695). Ghosal teaches a herbo-mineral composition from purified Shilajit containing an antioxidant (oligomeric dibenzo-α-pyrones), in synergistic combination with an extract of the *Emblica officinalis* plant containing tannoids (gallo/ellagi-tannoids), an added mineral supplement (iron, chromium, copper, zinc, or manganese) for treating mineral-deficient conditions, and excipients (page 2, paragraphs [0016] and [0022]; and page 4, paragraph [0034]). The antioxidant in the composition has a molecular weight ranging from about 450 to 2500 Daltons, preferably 500-700 Daltons (page 2, paragraph [0017]). The herbo-mineral composition is administered orally to children and adults (page 2, paragraph [0023]; and page 4, paragraph [0033]).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal (U.S. Patent Application No. 2003/0198695) as applied to claims 1, 5, 9-11, 22, 24-25, and 27

above, in view of Huang et al. (U.S. Patent Application No. 2003/0152588) and Ghosal (U.S. Patent 6,124,268).

Ghosal (U.S. Patent Application No. 2003/0198695) does not teach a phenolic antioxidant having no pro-oxidation activity and hydrolyzable tannins form obtained from the *Phyllanthus emblica* fruit.

Huang et al. teach compounds of Chinese traditional medicines (CTMs) show significant inhibition of lipid peroxidation (page 4, paragraph [0053]).

Ghosal (U.S. Patent 6,124,268) teaches gallo-ellagi tannins are obtained from the *Emblica officinalis* fruit (abstract).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the herbo-mineral composition of Ghosal (U.S. Patent Application No. 2003/0198695) to inhibit oxidation as well as to make tannins from the *Phyllanthus emblica* fruit because the compounds of CTMs of Huang et al. inhibit oxidation and the gallo-ellagi tannins of Ghosal (U.S. Patent 6,124,268) are obtained from the *Emblica officinalis* fruit and according to Huang et al. and Ghosal (U.S. Patent 6,124,268), the compounds of CTMs inhibit oxidation and the gallo-ellagi tannins are obtained from the *Emblica officinalis* fruit.

The motivation to combine the herbo-mineral composition of Ghosal (U.S. Patent Application No. 2003/0198695) to the CTMs of Huang et al. and the gallo-ellagi tannins of Ghosal (U.S. Patent 6,124,268) is that the compounds of Huang et al. inhibit oxidation and the compounds of Ghosal (U.S. Patent 6,124,268) are tannins obtained from the *Emblica officinalis* fruit.

Regarding *Phyllanthus emblica* as recited in the instant claim 13, it is disclosed in the instant specification that *Emblica officinalis* is synonymous with *Phyllanthus emblica* (page 8, paragraph 3).

9. Claims 2-3, 6-8, 12, 14-21, 23, 26, and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal (U.S. Patent Application No. 2003/0198695) in view of Huang et al. (U.S. Patent Application No. 2003/0152588) and Ghosal (U.S. Patent 6,124,268) as applied to claims 1, 4-5, 9-11, 13, 22, 24-25, and 27 above, in further view of Ghosal (U.S. Patent 6,440,436), Wang et al. (Diabetes, 2002, 51, Supplement 3, pp. S333-S342), and Boynton et al. (U.S. Patent 5,087,623).

Ghosal (U.S. Patent Application No. 2003/0198695) teaches oral administration of a herbo-mineral composition to children and adults on a daily dosing schedule (page 1, paragraph [0013] and page 2, paragraph [0018]).

Ghosal (U.S. Patent Application No. 2003/0198695) does not teach the antioxidant as oxygenated dibenzo-α-pyrone (DBP), the condition of Type 2 diabetes or glucose intolerance, the chromium content of the antioxidant-chromium complex, the chromium as trivalent, and the preparation of the antioxidant-chromium complex by a trivalent chromium salt.

Ghosal (U.S. Patent 6,440,436) teaches oxygenated dibenzo-α-pyrone (DBP) specifically (abstract).

Boynton et al. teach a treatment for maturity-onset diabetes comprising administering chromic picolinate to control high blood serum glucose levels and lipid levels including lowering blood serum LDL-cholesterol levels and raising blood serum HDL-cholesterol levels (abstract). The chromium is known to improve glucose tolerance (column 2, lines 19-20).

Boynton et al. also teach trivalent chromium in the amount of 200 μg of chromium or 12.5% chromium content (column 3, line 32 and column 7, lines 19-20). Additionally, the chromium picolinate is synthesized by combining picolinic acid and chromic chloride in deionized water, of which the final product (chromium picolinate) is air-dried (column 7, lines 3-13).

Wang et al. teach maturity-onset diabetes is a form of type 2 diabetes (p. S333).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the herbo-mineral composition of Ghosal (U.S. Patent Application No. 2003/0198695), the compounds of CTMs of Huang et al., and the gallo-tannins of Ghosal (U.S. Patent 6,124,268) to treat type 2 diabetes and to incorporate chromium into the phenolic-chromium complex because the oxygenated dibenzo-α-pyrone (DBP) of Ghosal (U.S. Patent 6,440,436), the teachings of Wang et al., and the chromium chloride of Boynton et al. are used to treat type 2 diabetes and to incorporate chromium by reaction with chromium chloride.

The motivation to combine the herbo-mineral composition of Ghosal (U.S. Patent Application No. 2003/0198695), the CTMs of Huang et al., and the gallo-tannins of Ghosal (U.S. Patent 6,124,268) to the oxygenated dibenzo-α-pyrone (DBP) of Ghosal (U.S. Patent 6,440,436), the teachings of Wang et al., and the chromium chloride of Boynton et al. is that the oxygenated dibenzo-α-pyrone (DBP) of Ghosal (U.S. Patent 6,440,436) and the teachings of Wang et al. treat type 2 diabetes and the chromium chloride of Boynton et al. incorporates chromium by reaction with chromium chloride.

Regarding chromium content in the complex, as recited in claims 6-7 and 26, it is noted that Boynton et al. teach providing chromium picolinate will yield a composition containing

12.5% chromium content, which closely meets the amount of chromium content set forth in claims 6-7 and 26. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of chromium picolinate provided in a composition, according to the guidance set forth in Boynton et al., to provide a composition having desired chromium content. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 4-5, 9-11, 13-16, 18, 20, 31, and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of Ghosal (U.S. Patent 6,124,268), claim 1 of Ghosal (U.S. Patent 6,290,996), claim 1 of Ghosal (U.S. Patent 6,362,167), and claim 8 of Ghosal (U.S. Patent 6,440,436). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of each of the Ghosal patents is directed to the extract of the fruit of the *Emblica officinalis* plant and claim 8 of Ghosal is the purified shilajit composition which consists essentially of oxygenated dibenzo-α-pyrones, which is the same extract of the fruit of the *Emblica officinalis* plant and the purified shilajit composition used in a composition for the treatment of a condition comprising a phenolic antioxidant-chromium complex in the instant claims 1, 4-5, 9-11, 13-16, 18, 20, 31, and 33. Thus the extract of the fruit of the *Emblica officinalis* plant and the purified shilajit composition are not patentably distinct between each of the Ghosal applications and the instant application.

11. Claims 1, 4-5, 9-11, 13-16, 18, 20, 31, and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of Ghosal (U.S. Patent 6,124,268), claims 1 and 5 of Ghosal (U.S. Patent 6,235,721), claim 7 of Ghosal (U.S. Patent 6,362,167), claim 1 of Ghosal (U.S. Patent 6,440,436), claims 1 and 2 of Ghosal (U.S. Patent 6,558,712), and claim 1 of Ghosal (U.S. Patent 6,869,612) in view of Ghosal (U.S. Patent Application No. 2003/0198695), Huang et al. (U.S. Patent Application No. 2003/0152588), Ghosal (U.S. Patent 6,124,268), Ghosal (U.S. Patent 6,440,436), Wang et al. (Diabetes, 2002, 51, Supplement 3, pp. S333-S342), and Boynton et al. (U.S. Patent 5,087,623) as applied to claims 1-27 and 30-35 above.

12. Claims 1, 4-5, 9-11, 13-16, 18, 20, 31, and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 26 of copending Application Ghosal (US 2005/0233942), claims 1, 3, 7-8 of copending Application Ghosal (US 2005/0282781), claims 18, 37, 41-43, 45-46, and 51-56 of copending Application Ghosal (US 2006/0062863), claims 1-2 of copending Application Ghosal (US 2006/0159784), and claims 20, 27, and 29-30 of copending Application Ghosal (11/493,185) in view of Ghosal (U.S. Patent Application No. 2003/0198695), Huang et al. (U.S. Patent Application No. 2003/0152588), Ghosal (U.S. Patent 6,124,268), Ghosal (U.S. Patent 6,440,436), Wang et al. (Diabetes, 2002, 51, Supplement 3, pp. S333-S342), and Boynton et al. (U.S. Patent 5,087,623) as applied to claims 1-27 and 30-35 above.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh